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10/501,035	05/02/2005	Fei Huang	D0185 PCT	8131

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EXAMINER	
LIU, SUE XU	

ART UNIT	PAPER NUMBER
1639	

NOTIFICATION DATE	DELIVERY MODE
11/16/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/501,035	HUANG ET AL.	
	Examiner	Art Unit	
	Sue Liu	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41 and 42* is/are rejected.

7)☒ Claim(s) *42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :10/4/04;5/6/05;5/10/06;9/6/07;10/30/07.

DETAILED ACTION

Claim Status

1. Claims 1-40 have been cancelled as filed on 9/6/07.

Claims 41 and 42 have been added as filed on 9/6/07.

Claims 41 and 42 are currently pending.

Claims 41 and 42 are being examined in this application.

Election/Restrictions

2. Applicants have canceled all claims and added new claims 41 and 42, which are examined in this application.

Priority

3. This application is filed under 35 U.S.C 371 of PCT/US031/01981 (filed on 01/17/2003), which claims priority to US provisional applications 60/350,061 (filed on 1/18/2002).

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-

filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/350,061, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

The instant claims recites a method of using expression profile of certain polynucleotides or polypeptides to indicate a cell's sensitivity to a protein kinase inhibitor. The instant claims recites several specific SEQ ID Nos such as SEQ ID NO: 204. However, the provisional application 60/350,061 does not appear to have support for the claimed method of using polypeptides with the listed SEQ ID Nos in the instant claims 41 and 42. For example, SEQ ID No:204 of the instant claim 1 is drawn to a polypeptide sequence. However, SEQ ID NO: 204 listed in the provisional application recites a polynucleotide sequence. The polynucleotide sequence recited in SEQ ID NO204 of the provisional also does not appear to be structurally the same to the polynucleotide of the instant claim 41 that encodes for the polypeptide of SEQ ID No:204 of the instant application. The said subject matter does not obtain the priority date of the provisional application, 60/350,061.

Thus, the effective filing date for the said subject matter of the instant claims is 1/17/2003.

Information Disclosure Statement

5. The IDS filed on 10/4/04, 5/6/05, 5/10/06, 9/6/07 and 10/30/07 have been considered. See the attached PTO 1449 forms.

Specification

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. MPEP 608.01.

Claim Objections

7. Claim 42 is objected to because of the following informalities: The phrase "a expression product" in line 2 of the said claim should be amended to recite "an expression product". Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter Rejection

9. Claims 41 and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 41 and 42 have been newly added and recite "while decreased expression of said gene expression product in said sample relative to a standard is indicative of resistance to a protein tyrosine kinase inhibitor". However, the instant specification does not appear to provide support for the claimed "decreased expression of said gene expression... is indicative of resistance". The citations pointed out by applicants (Reply, filed on 9/6/07) for support of the newly added claims do not appear to offer support for the said specific citation. For example Applicants pointed to the Tables (e.g. 3-6 and 10-12) of the instant specification, which Tables only indicate that the listed genes are "highly expressed" (i.e. increased expression) in resistant cells (see Table 12, for example). It is not clear which specific passage of the instant specification discloses that "decreased expression" indicates resistance.

If Applicant believes this rejection is in error, applicant must disclose where in the specification support for the entire scope of the amendment(s) and/or new claims can be found. As a result, Claims 41 and 42 represent new matter.

Second paragraph of 35 U.S.C. 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 41 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim language of Claims 41 and 42 are unclear and indefinite. For example, Claims 41 and 42 recite "while decreased expression of said gene expression product in said sample relative to a standard is indicative of resistance to a protein tyrosine kinas inhibitor", which recitation seems to contradict the definition and disclosure of the instant specification. The instant specification, for example, lists "polynucleotides" that are used to indicate "sensitivity/resistance" of cells to kinase inhibitors in various Tables. The instant specification discloses the "polynucleotides" are all "highly expressed" (i.e. increased expression) in resistant cells (see Table 12, for example), which are in direct contradiction with the recitation "decreased expression... indicative of resistance" of the instant claim. Thus, one of ordinary skill in the art would not be able to apprise the metes and bounds of the claimed invention. See MPEP 2173.03.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(Note: the instant claim numbers are in bold font.)

Imai

13. Claim 41 is rejected under **35 U.S.C. 102(b)** as being anticipated by Imai et al (Pathology International. Vol.51: 643-648; 8/2001; Publication date is 1 year prior to the above said effective filing date of 1/17/03.).

The instant claims recite "A method of identifying colon cancer cells that are either resistant or sensitive to a protein tyrosine kinase inhibitor comprising the step of determining the expression profile of an expression product from at least one informative polynucleotide in a colon cancer sample, wherein said at least one informative polynucleotide is the polynucleotide encoding bone morphogenetic protein 2 (SEQ ID NO:204), and wherein increased expression of said expression product in said sample relative to a standard is indicative of sensitivity to a protein tyrosine kinase inhibitor, while decreased expression of said gene expression product in said sample relative to a standard is indicative of resistance to a protein tyrosine kinase inhibitor".

The recitation "identifying colon cancer cells that are either resistant or sensitive to a protein tyrosine kinase inhibitor" in the preamble of **clm 41** is construed as intended uses of the instant claimed method for the purpose of the following prior art rejections, because the said recitations do not appear to impart structural limitations to the claimed method steps.

See MPEP 2111.02 II: "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)."

In this case, the body of the claims set forth all the method structural limitation of the claimed method. The body of the claim (e.g. Claim 41) recites "determining the expression profile of an expression product from at least one informative polyncleotide in a colon cancer sample..." That is the body of the claim recites all the required method steps/reagents including "determining the expression profile", "SEQ ID NO:204", "a colon cancer sample", etc.. The recitation of "identifying colon cancer cells that are either resistant or sensitive to a protein tyrosine kinase inhibitor" does not offer additional structural limitation to the claimed method, and only seems to provide the "intended result" (or use) of the process step in the body of the instant claims. That is the "determining expression profile" step of the specific recited polynucleotides (e.g. polynucleotide encoding SEQ ID NO:204) in a colon cancer cell would result in the identification of the "colon cancer" as either "resistant or sensitive to a protein tyrosine kinase inhibitor". This claim interpretation is supported by the instant specification where a cell's resistance/sensitivity to a kinase inhibitor is correlated to various gene expression profiles (e.g. p.19, lines 11+; Tables).

In addition, the underlined region of the recitation "wherein increased expression of said expression product in said sample relative to a standard is indicative of sensitivity to a protein

tyrosine kinase inhibitor, while decreased expression of said gene expression product in said sample relative to a standard is indicative of resistance to a protein tyrosine kinase inhibitor" in the instant claims 41 and 42 also do not appear to provide additional structural limitations such as additional method steps/reagents.

See MPEP 2106 II: "Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation." (emphasis in original);

See also MPEP 2111.04: "Claim scope is not limited by claim language that suggests or makes optional but does not require steps to be performed, or by claim language that does not limit a claim to a particular structure. However, examples of claim language, although not exhaustive, that may raise a question as to the limiting effect of the language in a claim are:

(A) "adapted to" or "adapted for" clauses;

(B) "wherein" clauses; and

(C) "whereby" clauses."

"... However, the court noted (quoting Minton v. Nat 'l Ass 'n of Securities Dealers, Inc., 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003)) that a 'whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.'". (emphasis added).

In this case, the phrase "relative to a standard" (i.e. comparing the sample cell gene expression to a standard) can be construed as another "process step" that is "positively recited". The recitations such as "indicative of sensitivity to a protein tyrosine kinase inhibitor" "simply expresses the intended result of the a process step positively recited".

Therefore, the instant claim 41 can be construed to recite a method comprising the following method steps/reagents:

A.) determining the expression profile of at least one polynucleotide comprising a polynucleotide encoding for a protein of SEQ ID NO: 204 (or bone morphogenetic protein 2);

B.) comparing the expression profile of A) to "a standard".

The following art rejection is discussed in light of the above claim interpretation.

Imai et al, throughout the publication, teach monitoring gene expression profile of various genes in colon cancer samples (e.g. Abstract). The reference teaches determining the gene expression of various bone morphogenetic proteins (BMPs) in colon tumors and/surrounding cells from colon tissues by using immunohistochemical staining of the proteins (i.e. expression products) (e.g. Figure 1; pp.644-645), which read on the steps of determining gene expression profile of an expression product of an informative polynucleotide as recited in **clm 41**.

The reference also teaches comparing the gene expression of BMP-2 gene in various cells such as tumor cells and "mesenchymal fibroblast cells" (e.g. Figure 4; p.645, para 2), which read on the comparing with "a standard" of **clm 41** because the mesenchymal fibroblast cells can be considered as a standard as the term "a standard" is broadly used in the instant disclosure. The reference also inherently teaches BMP-2 has the amino acid sequence listed in SEQ ID NO:204, as evidenced by the instant disclosure reciting BMP-2 protein has the sequence listed in SEQ ID NO:204 (See p.104, Table 3 of the spec.). The reference teaches that the Bone Morphogenetic

Proteins expressed are human proteins (e.g. Abstract), and the instant specification also teaches that the BMP-2 protein is of human origin as reflected by its GenBank accession number "M22489" (see p.104, Table 3) and citation in the instant Sequence Listing. Thus, the BMP-2 protein of the reference inherently comprise the sequence recited in SEQ ID NO:204 without evidence to the contrary.

As discussed above, the recitation "wherein increased expression ... is indicative of sensitivity to a protein tyrosine kinase inhibitor, while decreased expression ..." is construed as intended use or result of the instant claimed method. See MPEP 2111.04: "However, the court noted (quoting Minton v. Nat 'l Ass 'n of Securities Dealers, Inc., 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003)) that a 'whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.'" (emphasis added).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Imai and Roth

15. Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imai et al (Pathology International. Vol.51: 643-648; 8/2001; Publication date is 1 year prior to the above said effective filing date of 1/17/03.).), in view of Roth et al (US 20020051978; 5/2/02; filed on 2/16/01; or earlier priority date).

The instant claims are construed the same as the discussed above under the rejection over the Imai reference alone.

Imai et al, throughout the publication, teach monitoring gene expression profile of various genes in colon cancer sample, as discussed above.

Imai et al do not explicitly teach using an additional polynucleotide with sequences recited in the specific SEQ ID Nos as recited in **clm 42**.

However, Roth et al, throughout the publication, teach identifying cells that are sensitive to cancer therapeutic agents using gene expression profile. (e.g. Abstract). The reference teaches measuring gene expression in various cancer cells including colon/colorectal tumor cells (e.g. p.5, [0061]). The reference also teaches the gene markers used for assessing gene expression profile to determine drug sensitivity includes the polynucleotide of GenBank accession number "D13413" (e.g. Tables 6 and 8), which the GenBank accession number D13413 corresponds to the polynucleotide encoding the protein of the instant SEQ ID No:247 of **clm 42**, as evidenced by Table 3 of the instant specification. The reference also teaches that the gene with accession

number D13413 is differentially expressed in cells that have differential response to cancer therapeutic drugs. (e.g. Table 6; p.29).

Therefore, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to determining gene expression profiles of various genes of interest.

A person of ordinary skill in the art would have been motivated at the time of the invention to monitor gene expression profile of a polynucleotide with GenBank accession number D13413 (or the polynucleotide encoding for SEQ ID NO:247) in colon/colorectal cancer cells, because the marker, D13413 provides the advantages of having differential gene expression profile in cells with different reactivity (sensitivity or resistance) to cancer therapeutic agents, as taught by Roth et al. In addition, one of ordinary skill in the art would have been motivated at the time of the invention to use D13413 polynucleotide in addition to BMP-2 gene for achieving the predictable result of measuring differential gene expression profile in colon/colorectal cancer cells.

A person of ordinary skill in the art would have reasonable expectation of success of achieving such modifications since both Imai et al and Roth et al have demonstrated the success of measuring gene expression profiles (e.g. measuring gene expression products) in colon cancer cells.

Shyjan, Imai and Roth

16. Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Shyjan et al (US 20020006613; 1/17/2002; 1/17/2002; filed 8/13/2002; or earlier priority date),

in view of Imai et al (Pathology International. Vol.51: 643-648; 8/2001) and Roth et al (US 20020051978; 5/2/02; filed on 2/16/01; or earlier priority date).

The instant claims are construed the same as the discussed above under the rejection over the Imai reference alone.

Shyjan et al, throughout the publication, teach using gene expression profile of markers (or nucleic acids) to determine if cancer cells are sensitive or resistant to a therapeutic agent. (e.g. Abstract). The reference teaches determining gene expression levels from cancer cell samples (e.g. p.1, [0008]+; claims 1+; p.3, [0030]+) by measuring gene expression products such as mRNA levels (e.g. pp.5-6, [0048]+), which read on the steps of determining gene expression profile of an expression product of an informative polynucleotide as recited in **clm 41**. The reference also teaches comparing the expression profile of the genes of colon cancer cell lines to standards (e.g. pp.19-20; [0212]).

Shyjan et al do not explicitly teach monitoring the gene expression of BMP-2 (i.e. SEQ ID NO:204) as recited in **clm 41**, and another additional polynucleotide with sequences recited in the specific SEQ ID Nos as recited in **clm 42**.

However, Imai et al, throughout the publication, teach monitoring gene expression profile of various genes in colon cancer samples, as discussed above. The Imai reference also teaches that BMP-2 gene is differentially expressed in colon tumor tissues.

Roth et al, throughout the publication, teach identifying cells that are sensitive to cancer therapeutic agents using gene expression profile. (e.g. Abstract). The reference teaches measuring gene expression in various cancer cells including colon/colorectal tumor cells (e.g. p.5, [0061]). The reference also teaches the gene markers used for assessing gene expression

profile to determine drug sensitivity includes the polynucleotide of GenBank accession number "D13413" (e.g. Tables 6 and 8), which the GenBank accession number D13413 corresponds to the polynucleotide encoding the protein of the instant SEQ ID No:247 of **clm 42**, as evidenced by Table 3 of the instant specification. The reference also teaches that the gene with accession number D13413 is differentially expressed in cells that have differential response to cancer therapeutic drugs. (e.g. Table 6; p.29).

Therefore, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to determining gene expression profiles of various genes of interest in colon cancer tissues.

A person of ordinary skill in the art would have been motivated at the time of the invention to monitor gene expression profile of BMP-2 gene in colon/colorectal cancer cells, because BMP-2 gene provides the advantage as a useful and unique marker that is differentially expressed in the colon tissues.

A person of ordinary skill in the art would have been motivated at the time of the invention to monitor gene expression profile of a polynucleotide with GenBank accession number D13413 (or the polynucleotide encoding for SEQ ID NO:247) in colon/colorectal cancer cells, because the marker, D13413 provides the advantages of having differential gene expression profile in cells with different reactivity (sensitivity or resistance) to cancer therapeutic agents, as taught by Roth et al. In addition, one of ordinary skill in the art would have been motivated at the time of the invention to use D13413 polynucleotide in addition to BMP-2 gene for achieving the predictable result of measuring differential gene expression profile in colon/colorectal cancer cells.

A person of ordinary skill in the art would have reasonable expectation of success of achieving such modifications since Shyjan et al, Imai et al and Roth et al have demonstrated the success of measuring various gene expression profiles (e.g. measuring gene expression products) in colon cancer cells.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 41 and 42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 41, 43 and 44 of copending Application No10/348,119 (US 20070166704). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed method of the '119 co-pending application read on the instant claimed invention.

Claim 41 of the '119 application recites: "A method of identifying colon cancer cells that are either resistant or sensitive to a protein tyrosine kinase inhibitor comprising the step of determining the expression profile of an expression product from an informative polynucleotide predictor set in a colon cancer sample, wherein said informative polynucleotide predictor set consists of: SEQ ID NO:1... SEQ ID NO:3...", which read on the claim limitation of the instant **clms 41** and **42** because SEQ ID Nos. 1 and 3 encode for the same proteins of SEQ ID Nos:202 and 204 of the instant claims. (See Table 3 of the '119 application and Table 3 of the instant spec. for SEQ ID No correspondence between the specific polynucleotides and polypeptides).

Similarly, **claims 43** and **44** recite method using the specific SEQ ID Nos, which read on the instant claimed method of **clms 41** and **42**.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sue Liu/
Patent Examiner, AU 1639
11/10/07